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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

97-PHI-28

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

GEN. SPEC.
RELEASE
F# _____ DATE 6/12/97
Reviewed by:

June 6, 1997

George W. Smith, President
Tri-County Medical Oxygen, Inc.
[redacted] Bedford Street
Clarks Summit, Pennsylvania 18411

Dear Mr. Smith:

On April 9, 15 & 18, 1997, U. S. Food and Drug Administration Investigator Ann Marie Karnick conducted an inspection of your compressed medical gas facility located at 335 Bedford Street, Clarks Summit, Pennsylvania. The liquid oxygen filled by your firm is a drug within the meaning of 201(g) of the Federal Food, Drug, and Cosmetic (FD&C) Act and as such is subject to the requirements of Title 21 Code of Federal Regulations (21 CFR).

At the conclusion of the inspection Investigator Karnick issued a form FDA-483, Inspectional Observations, to your Business Manager, Anthony R. Summa, and discussed the observations with him. A copy of this form is enclosed for your information. This inspection revealed violations as follows:

The drug product manufactured at your firm is adulterated under Section 501(a)(2)(B) of the FD&C Act, in that, your operations do not conform to Current Good Manufacturing Practice regulations as described in 21 CFR; specifically,

1. Failure to assay for identity and strength 180 liter liquid oxygen vessels prior to release for distribution [21 CFR § 211.165(a)]; for example, lot #'s [redacted], [redacted], [redacted], [redacted] and [redacted].

2. Failure to assay for identity and strength one cylinder from each six cylinder batch of transfilled oxygen gas prior to release for distribution [21 CFR § 211.165(a)]; for example, lot #'s [redacted], [redacted], and [redacted].

3. Failure to establish adequate batch production and control records for each batch of drug product produced, in that, these records lack documentation of supervisory review [21 CFR § 211.188(b)(11)].

We would also like to note that testing, as per your firm's written procedures, requires the use of the [redacted] analyzer; and that, employees must be adequately trained in all manufacturing procedures. Additionally, labeling requirements must be fulfilled for all gas and liquid oxygen products produced.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. As top management it is your responsibility to ensure adherence to each requirement of the FD&C Act and all federal regulations.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct these violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to the attention of William J. Forman, Compliance Officer, at the address noted on the letterhead.

Sincerely,

Diana J. Kolaitis
District Director
Philadelphia District

Enclosure:
Form FDA-483

cc: Robert E. Bastian, Director
Division of Primary Care and Home Health Services
Pennsylvania State Department of Health
132 Kline Plaza
Harrisburg, Pennsylvania 17104